



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,842	03/20/2006	Ania Muntau-Heger	30610/30032	5018

90849 7590 09/17/2010
Marshall, Gerstein & Borun LLP (Biomarin)
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606

EXAMINER

VAKILI, ZOHREH

ART UNIT	PAPER NUMBER
----------	--------------

1614

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

09/17/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@marshallip.com
mflores@bmrn.com
lbigornia@bmrn.com

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/539,842</p>	<p>Applicant(s) MUNTAU-HEGER ET AL.</p>	
	<p>Examiner ZOHREH VAKILI</p>	<p>Art Unit 1614</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 August 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 45-55.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

Continuation of 3. NOTE: Applicant adds new limitations to the claims that requires further search and/or consideration. Specifically, please see claim 45, in which Applicant has added the limitation "patient is identified as having a mutation". This newly added limitation restricts the method for long term treatment of condition.

Continuation of 11. does NOT place the application in condition for allowance because: The amendment will not be entered into the record because of the addition of new limitations that have not been previously considered and/or searched. However, in the interest of compact prosecution, applicant's remarks are considered, but are not persuasive for the reasons previously made of record in the final rejection (see pages 9-15) and in further view of the following comments: Applicant's arguments are not persuasive, Applicant discusses limitations that are not required by the instant claimed invention. The claims requires the administration of the general formula in the treatment of PKU. Nichols teach pteridines known as pterins which are analogs of tetrahydrobiopterin, to pharmaceutical formulations containing them, and their use in the treatment of Parkinsonism (and other diseases caused by a deficiency of biogenicamines (e.g., catecholamines and serotonin) in the brain and the peripheral nervous system) and the tetrahydrobiopterin-deficient phenylketonurias (atypical PKU) (see col. 1, lines 7-17). This enzyme requires tyrosine, oxygen and a reduced pterin cofactor, tetrahydrobiopterin (BH4), for activity. Levels of this cofactor are severely diminished in Parkinson's disease (see col. 2, lines 21-31), this amendment is not being entered into the record and, accordingly, applicant's remarks related to the obviation of the rejection by such an amendment are not persuasive. Accordingly, the amendment will not be entered for the reasons above and claims 45-55 remain rejected for the reasons of record set forth in the final rejection of 5/13/2010.

/Zohreh Vakili/
Patent Examiner Art Unit 1614